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MEMORANDUM

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SUBJECT: Addendum to the Malathion Drinking Water Assessment (DWA) Modeling Assumptions and Potential Refinements

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EFED previously completed a Tier 1 and a Tier 2 refined Drinking Water Assessment (DWA) for all registered malathion uses using a suite of surrogate scenarios representing 17 agricultural uses and 2 non-agricultural uses which are the highest malathion use patterns[1]. Initial Tier 1 estimated drinking water concentrations (EDWCs) were incorporated into the Health Effects Division's (HED) Dietary Risk Assessment but because the initial dietary assessments suggested potential risk from drinking water, a Tier 2 DWA was completed. In that Tier 2 DWA, EFED incorporated several refinements including: use of both National and Regional percent cropped

[1] Drinking Water Assessment for Registration Review of Malathion. A. Shelby. August 13, 2015. DP 420234.

area (PCA) adjustments, a refined residential scenario that altered assumptions of percent impervious surface treated, alternative assumptions of key fate model inputs, alternative application timing, and updated fate information on oxon formation. At the time of completion these refinements, EDWCs were reduced below the EPA level of concern (LOC) for the human health dietary risk assessment. Subsequent to the completion of the initial dietary assessment, EPA determined that there is insufficient information to remove the 10x FQPA Safety Factor due to uncertainties in the human dose-response for neurobehavioral effects, and therefore, several uses which passed the initial dietary assessment now exceed the EPA's LOC for dietary risk. The EDWCs taken from the Tier 2 DWA are summarized in Table 1.

Of these uses, the highest EDWC evaluated in the dietary model was the MS Cotton use at 84.7 ppb which yielded an exceedance of the acute level of concern (690% of the aPAD) for water only. (The Florida citrus use at 92.7 ppb was not included in the Dietary Assessment but should yield comparable risk). Other uses explored in the dietary modeling (including food and water) were 350% of the aPAD for strawberry with a peak EDWC of 59.9 ppb, 240% for cabbage with a peak EDWC of 47.2 ppb, 160% for cotton with a peak EDWC of 84.7 ppb, and less than 1% for the two cotton and cherry ULV uses with a peak EDWCs of 43 and 27 ppb, respectively. Other scenarios yielded much lower EDWCs with many scenarios in the 10 to 20 ppb range (see Table 1).

Table 1. Surface water EDWCs for Malathion calculated using Surface Water Concentration Calculator (SWCC)

Scenario	1-in-10-year Peak (ppb)	1-in-10-year Annual Average (ppb)	30 year Mean (ppb)
FL Citrus	92.7	0.153	0.0769
MS Cotton	84.7	0.211	0.109
FL Strawberry	59.9	0.224	0.154
GA Peach	49.4	0.118	0.0648
FL Cabbage	47.2	0.316	0.189
MS Cotton (ULV)	43.2	0.713	0.435
WA cherry[4]	35	0.368	0.272
GA Pecan	32.2	0.0734	0.0364
WA cherry[4] (ULV)	27	1.46	1.31
FL Tomato	24.1	0.133	0.096
CA Lettuce	22.3	0.149	0.0965
CA Strawberry	20.8	0.19	0.154
TX Sorghum	18.8	0.051	0.0276
TX Peach[2]	17.5	0.0797	0.0464
KS Alfalfa[1]	16.3	0.053	0.0381
FL Avocado	11.8	0.0343	0.0327
OR Pear	10.2	0.119	0.091
WA Asparagus[3]	10	0.116	0.0909

Scenario	1-in-10-year Peak (ppb)	1-in-10-year Annual Average (ppb)	30 year Mean (ppb)
MN Alfalfa	9.8	0.0446	0.0329

[1] KS sorghum scenario used
[2] GA peach scenario used
[3] OR mint scenario used
[4] OR apple scenario used

Although a Tier 3 DWA has not been conducted, there are additional assumptions and associated uncertainties within the Tier 2 DWA which with additional information, would allow for further refinements of the EDWC. For those uses with dietary exceedances just above 100% of the aPAD, simple refinement such as a small rate reduction may change the risk profile. For some higher exposure uses (e.g. cherry), individual refinements may reduce but not eliminate risk, but consideration of multiple refinements could change the risk profile. There are a number of assumptions incorporated into any DWA that may result in an over-estimation of exposure that remain with the Malathion DWA and could be refined with additional information. These include the assumption of label maximum rates and number of applications vs. what is typically being used, selection of environmental fate inputs, timing of applications and the assumption of selecting a single application date for larger watersheds, the percent of cropped area represented by a specific use (e.g., percent cherries within the orchard PCA), and percent of crop treated (PCT).

Several of the environmental fate assumptions (e.g., selection of aerobic soil metabolism input) are documented and the impact of alternative approaches are explored in the Tier 2 DWA, which can result in higher or lower estimation of exposure in select situations. Other assumptions not fully discussed but described below could help further refine the DWA and associated EDWCs for many of the uses exceeding EPA's LOC if additional information were available. Other assumptions such as the spatial variation of exposure across the landscape and its relationship to sources of surface water used by Community Water Systems (CWS) were implied in the modeling approach using multiple scenarios but could be expanded upon as described below.

More detail on each of these and the type of information that could reduce the uncertainty due to each are discussed below.

Typical Use Information

OPP's Biological and Economic Analysis Division (BEAD) provides information on typical use including average application rates, number of application and timing of application. For the August 2015 assessment, typical use information for malathion was provided in 2014. Typical use information can significantly reduce predicted exposures depending on the use site. For example, BEAD's analysis indicated that for the cherries (the use with the highest exceedance in the Dietary Assessment), the maximum labeled use rate is 1.75 lbs ai/acre per application with 4 applications allowed, while the typical rate is 0.5 lb ai/acre per application with 2.5 applications per year. Although not linear, consideration of alternative assumptions of typical use regarding the application rate, number of applications, and intervals would yield a roughly 3 to 4 fold reduction in EDWCs as compared to maximum labeled uses which could reduce the maximum %aPAD to roughly 200%.

While this is a significant reduction in exposure, it alone would not reduce dietary risk to below the level of concern. It is also critical to remember that a typical, or average, application rate derived from a distribution of application information means that for most uses, there are a significant number of applications occurring at rates higher than the typical rate. Concentrations generated by typical and maximum label rates provide a range in potential EDWCs for these uses.

Timing of Applications

In the Malathion DWA, EFED considered the timing of application by selecting the month with the most total precipitation in which applications could reasonably occur. However, because of its relatively short half-life, application date selection is a sensitive parameter for malathion that can result in a 2X to 3X difference in 1-in-10-year peak EDWCs given a two-day difference in application date. These differences in EDWCs are driven by the proximity and magnitude of specific precipitation events relative to application date. In the DWA, 40 % of peak concentrations of more than 20 ppb result from precipitation events on the day of malathion application and 70% occurred due to applications on the day of or the day following malathion application in the Mississippi Cotton scenario. Peak EDWCs associated with these events are as high as 123 ppb. The highest peak concentration from a run-off event two or more days from last application is found to be 77 ppb.

Additionally, refinement could include identifying the most typical time for application. Although this refinement may lower EDWCs, it may also result in an increase in EDWCs if the refined application day happens to occur during or shortly before precipitation events. Often this has a benefit when the application window is adjusted to reflect a more realistic time when the pesticide is applied vs. what has been assumed.

Due to malathion's rapid metabolism in aerobic soil (i.e. 1 day), exposure is significantly diminished with an additional day prior to a run-off event. Given that growers would be reluctant to make a pesticide treatment knowing that rain was predicted in the near future, it is unlikely that these exposures would commonly occur. None-the-less, it is possible that these types of exposures could be reduced with label language that would preclude applications occurring within 24/48 hours of a forecasted rainfall event. Modeling this type of limitation could be effective for reducing malathion EDWCs or for reducing EDWCs for pesticides with similar rapid degradation. For pesticides with greater persistence, the impact of application timing in relation to rainfall will likely be minimized.

Similar to the use of typical application rates and intervals, information is usually available on the range in timing of applications. Where information is available for larger watersheds, it is possible to adjust the selection of a single application date (it is appropriate to assume a single date for smaller watersheds) to an application window. The Tier 1 and Tier 2 DWA assumes that all applications in a watershed occur on the same day each year for 30 years. However, it is reasonable to assume that, for a larger watershed, not all growers will apply a pesticide on the same day and the applications can be apportioned across a window of time to better reflect practices in larger watersheds.

PCA (percent cropped area) Assumptions

PCAs are employed in all EFED drinking water assessments in a stepwise fashion. At Tier 1, the most conservative national PCA is employed for any use being assessed. Subsequent refinements can include individual use specific PCA and regional PCA. In all cases, the impact of the PCA on the EDWC is linear. For example, when a PCA of x% is applied to an EDWC for any use, the resulting EDWCs are reduced by x%. Several assumptions are inherent in the PCA values used by OPP. First, the PCA values were selected from a distribution of watershed/cropped area combinations within each regional hydrologic area (represented by HUC2 major basins). The highest PCA from each distribution was selected to represent that region in order to provide a conservative adjustment factor. What this means is that there can be areas across that individual region where the PCA for a particular use, or uses, is less than the default value (national or regional); however, it is difficult to define those areas for assessment purposes.

One other important consideration with PCA use is that the PCAs for many minor uses (e.g. cherries) are represented by aggregated uses (e.g. orchards) that likely over-estimate the footprint on the landscape for that use. Using the citrus example (which yields the highest malathion EDWC), the PCA used was for orchards. The orchard PCA represents an aggregation data layer from the National Landcover Data Layer (NLCD) adjusted using specific information from USDA data on orchard acreage. For citrus in Florida, the aggregated orchard PCA is probably a reasonable representation of the footprint for citrus since it dominates orchard type use sites; however, in other parts of the country where citrus may be present, the orchard PCA can represent an over-estimation of that use pattern. If accurate information were available on the distribution of individual crops such as citrus within the broader aggregated use category (i.e., orchards), the estimates could be refined depending on the quality and accuracy of the information. This refinement is most applicable for perennial uses such as orchards and vineyards and less applicable to annual crops as specific crops may change over shorter durations.

Finally, it is important to understand that there are limitations with the underlying data used to derive the national and regional PCAs. First, there are significant national security issues with the use of intake locations and their associated watersheds for CWS. Given these concerns, public presentation of these data is generally limited. EPA cannot release either the intake location or its associated delineated watershed to pinpoint the intake location. Second, the underlying spatial data sets used to define the potential footprint of use and the watershed boundaries have differing levels of uncertainty. Specific examples include errors of omission and commission with landcover data and boundary delineation errors. Importantly, the impact of these uncertainties are greater for smaller watersheds which can often have some of the highest PCAs among all watersheds in a region. For these reasons, EPA believes that the available data allow us to identify the characteristics of potentially vulnerable watersheds. However, due to limitations in the CSW intakes dataset, it is not possible for EPA to identify individual watersheds and should not be used to assess drinking water supplies on an intake-by-intake basis.

Spatial Variability

Though not all modeled uses were considered in the Dietary Risk Assessment, the variation in exceedances for the scenarios considered above indicate that, effectively, any EDWC in the 10 to 20 ppb range or lower would be at or below 100% of the aPAD without any further refinements. This is a key concept because it is important to recognize that, while individual uses exceed the dietary LOC, many uses do not, suggesting that a spatial component to risk should be considered. Given that most malathion use since the abatement of the Boll Weevil Eradication Program is on minor crops, which tend to have a limited geographic area, not all surface water Community Water Systems (CWS) are going to have the same exposure via drinking water. See the USGS map on current malathion use pattern for a representation of this spatial variability across the US. Figure 1 is derived using GfK data which is presented as a qualitative expression of use to demonstrate the importance of the spatial variability in malathion use across the landscape and provide spatial context for the EDWCs. Based on this information, there are significant areas of the country where the EDWCs presented above may not be relevant.

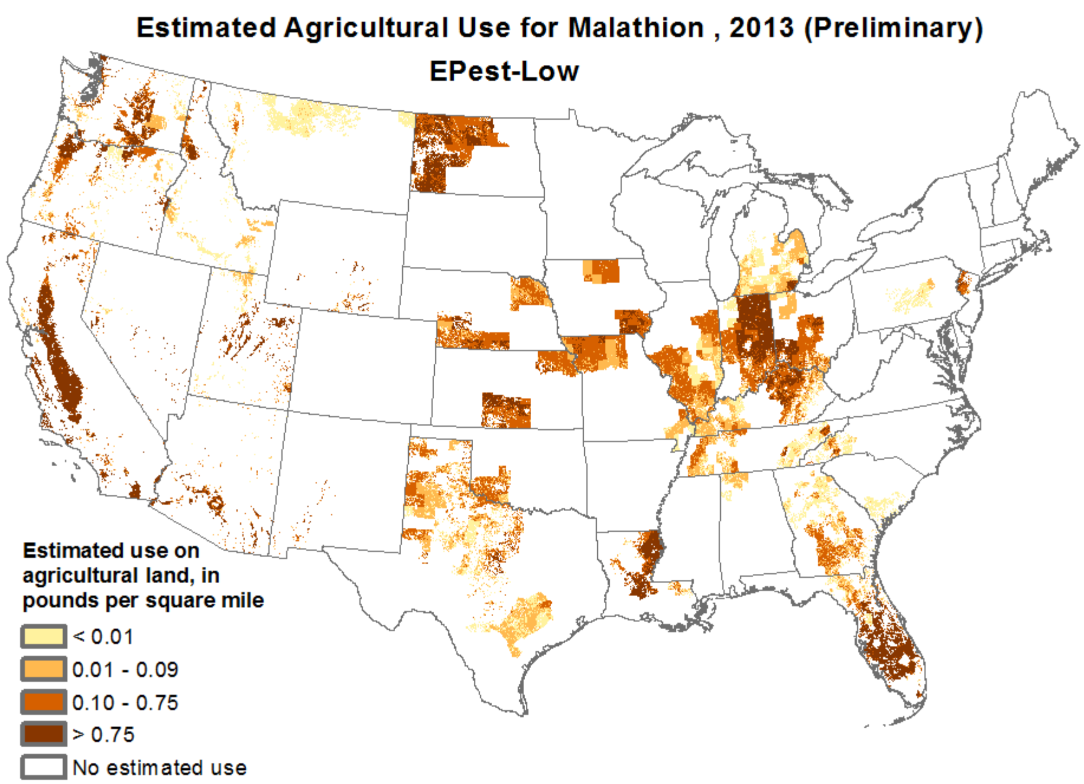

Figure 1. USGS map from 2013 showing a snapshot in time of the footprint of the highest potential Malathion use areas

A shift in malathion use patterns over time is depicted below in Figure 2, based on a USGS graph derived from GfK (Gesellschaft für Konsumforschung) proprietary survey data. For those uses that do exceed EPA's LOC, there are likely selected areas of the country where exposures would result in an exceedance. USGS maps derived from GfK from 2009 to 2013 (the latest five years of available data) show consistent use of malathion in Florida, the Mississippi River Delta, Texas, the Central Valley of California, and the Pacific Northwest. In these high usage regions, use is consistent with the modeled assumption that applications are repeated every year. Although not shown graphically in Figure 1, it is expected that all other regions of the conterminous United States have had at least sporadic usage of malathion in the five year period given the shifting pattern over time and the limited amount of information available on non-agricultural use of malathion.[2] In these lower usage regions, modeled assumptions of applications repeated annually do not align with observed repetition of applications.

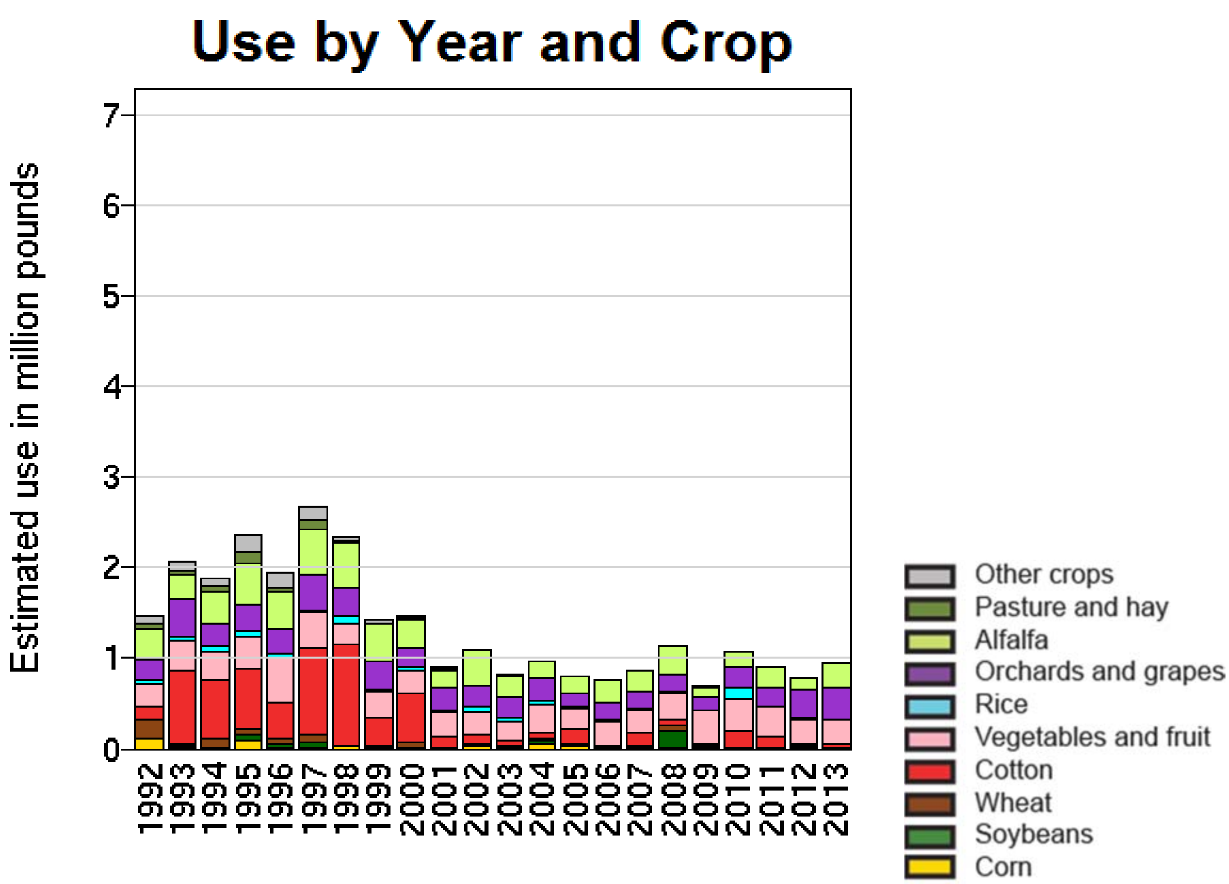

Figure 2. USGS map of the temporal shift of Malathion use over time

A final example of the spatial context can be demonstrated using the cherry example. The following figure shows where sweet cherries are grown in the US using Ag Census data from

[2] https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2013&map=MALATHION&hilo=L

2012. This figure demonstrates that sweet cherries are found predominantly in the northern tier of the US with heavy concentrations of acreage in the Pacific Northwest. This demonstrates that a spatial context is a key consideration when viewing EDWC particularly when the highest exposures ae associated with specialty crops.

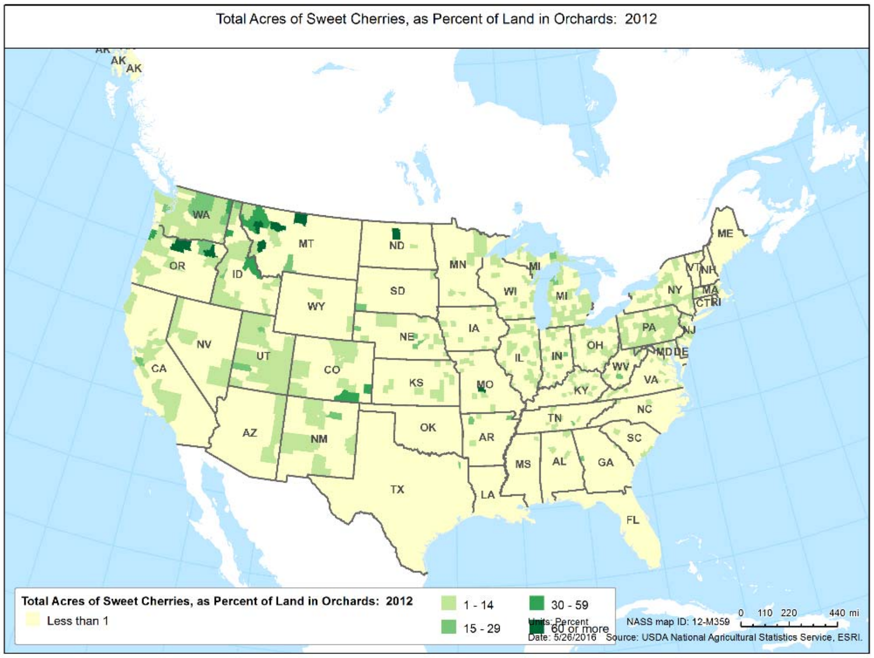

Figure 3. USDA map of Cherry acreage from Ag Census

Percent Crop Treated

Percent Crop Treated (PCT) represents the portion of a particular use site where the pesticide is actually applied. PCT is derived like typical application and timing information from information on actual applications occurring within a defined geography and is included in the BEAD analysis. Using cherries as an example, if an area of the country has 100,000 acres of cherries and a pesticide is applied to only 22,000 of the total 100,000 acres, the PCT for that pesticide and crop would be 22%. Because PCT is typically available to EPA from surveyed data (e.g. GfK) and is collected at a scale that exceeds the area of most watersheds (e.g. Crop Reporting District (CRP)), there is a challenge in knowing where within the area the data were collected from the use that occurred. See Figure 4 for a map of USDA CRP.

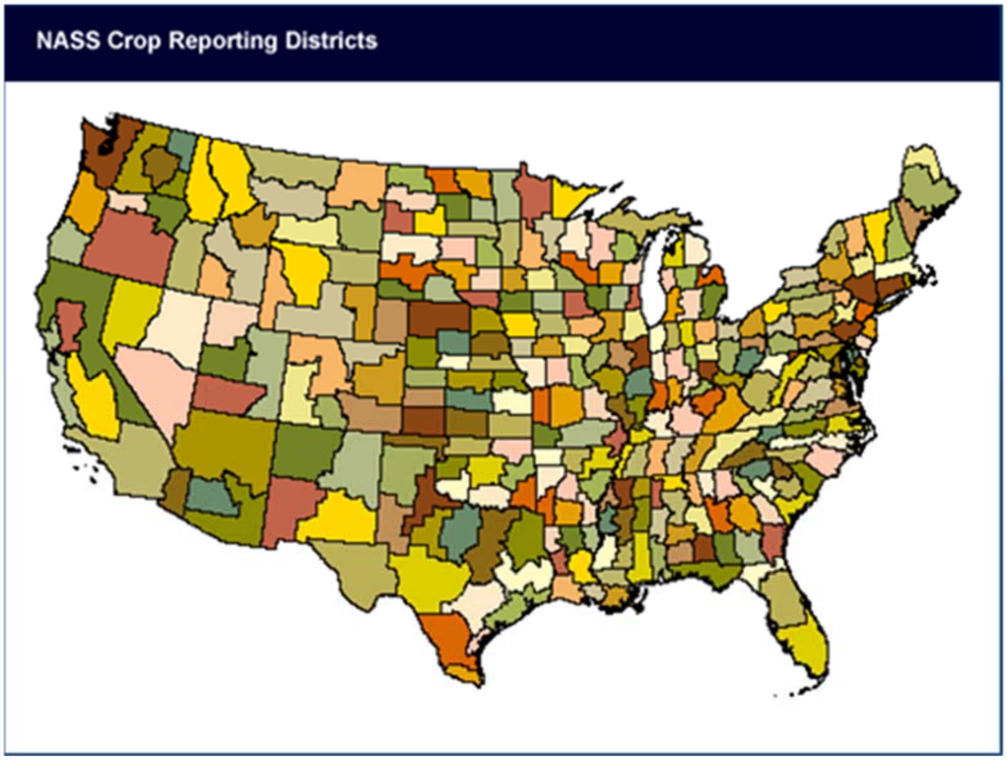

Figure 4. USDA map of Crop Reporting Districts

Taking the cherry example, where the PCT is 22%, it is difficult to know if that 22% of use was clustered in an area that overlaps with a subset of individual watersheds or is spread out over a wide area. For instance, an insecticide used in response to an outbreak of a specific pest will target the finite area of pest pressure, which is unlikely to be evenly distributed across the use area. For this reason, EFED does not typically use PCT as a refinement; however, it could be considered for characterization of the potential range in EDWCs on a case-by-case basis depending on the quality of the data.

Scenario Assumptions

The Pesticide Root Zone Model (PRZM) is EPA's principal model for assessing aquatic exposure for both human health and ecological risk assessments. PRZM is a field scale model that for human health represents a small highly vulnerable watershed whose receiving waterbody is a reservoir used for drinking water. A key concept when modeling with PRZM is the field scenario. EPA employs a suite of PRZM scenarios representing combinations of soil, cover type, agronomic and climatic conditions. While each scenario requires many inputs, EPA's sensitivity analysis[3] has shown that model output is driven by the selection of a few key inputs. In addition, the FIFRA Environmental Modeling Task Force (FEMVTF) also determined that the most important inputs are the runoff curve number, aerobic soil metabolism,

[3] See Section 2.3 of USEPA OPP's SAP Background Document on the Development of a Spatial Aquatic Model (SAM) for Pesticide Assessments for a summary of previous sensitivity analyses for PRZM. The document is available through the Federal Docket at https://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPP-2015-0424.

adsorption/desorption, soil organic carbon fraction, and rainfall during the key period when the pesticide is on the field[4]. Typically, EPA selects values for these inputs that are conservatively skewed high but not the highest possible value. For example, curve number is the main driver for runoff amount but is limited to four main choices based on hydrologic soil type. Typically, EPA selects a curve number that is at the high end but not the highest possible scenario. For example considering corn, it is known that in a few places corn can be grown on high runoff prone soils (i.e., hydrologic soil group D soils) but the majority of EPA's corn scenarios are C soils. C soils are still high runoff potential soils but provide a better representation of much of corn growing soils. Other inputs are similarly skewed to the high end of vulnerability but not the highest possible value. Taking soil metabolism as another example, EPA typically gets data on a very limited number of soils while there are thousands of agricultural soils in the US. EPA calculates a 90^{th} % of the mean to conservatively represent a high end soil because it is not possible to test all agricultural soils. Occasionally, EPA has only a single soil metabolism value in which case the value is multiplied by three because analysis has shown that this roughly approximates the 90^{th} % of the mean that would be derived with a more robust data set. These concepts are critical when considering that EPA uses the scenarios and other inputs to represent thousands of possible combinations of those inputs with a limited amount of data.

Drinking Water Treatment

Exposure of pesticides in source water can result in exposure to humans via consumption of drinking water. Typically drinking water from surface water sources is run through a Community Water System (CWS) and can experience multiple types of treatment processes. Treatment processes can vary across CWS facilities and spatially across the US. Some treatment processes can be effective at reducing some pesticide exposures dramatically (such as granular activated carbon); however, many treatment process can have little or no impact on pesticide exposure. These processes are not uniformly applied across all CWS and are not uniformly effective at reducing exposure. In addition, some processes such as chlorination can result in the conversion of a pesticide to a more toxic degradate (e.g. oxon)[5].

The effectiveness of drinking water treatment processes on pesticide removal depends upon the environmental fate properties of the pesticide. For instance, with typical residence times in CWS are on the order of 24 to 48 hours, a pesticide that degrades rapidly might be present in source water but degrade before exiting the treatment process. However, any pesticide whose half-life is greater than 24 to 48 hour is likely to still be present for human consumption.

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[4] Jones, R.L., and M.H. Russell (ed.). 2001. FIFRA Model Validation Task Force Final Report. The FIFRA Environmental Model Validation Task Force.

[5] A more comprehensive evaluation of the effects of drinking water treatment processes on different pesticide classes can be found in USEPA OPP's ***Finalization of Guidance on Incorporation of Water Treatment Effects on Pesticide Removal and Transformations in Drinking Water Exposure Assessments***, available online at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/finalization-guidance-incorporation-water-treatment.

For malathion specifically, the Drinking Water Assessment (DWA) indicated that chlorination does cause the formation of an oxon degradate (i.e. malaoxon). Laboratory tests have shown that this oxon degradate is likely to persist both in water and the treatment system for a sufficient amount of time to still be present in treated water and available for consumption. For this reason, EPA accounted for the presence of the oxon degradate which is more toxic in its assessment.

Monitoring Data

One final consideration is how modeled EDWCs compare with available monitoring data. For malathion, EFED is not aware of any data from surface water CWS; however, there is a large amount of data from ambient surface water. Most of these data are not targeted to malathion use patterns but are useful to compare against modeled values. Non-targeted monitoring typically provides a lower bound on exposure, and while the available data are not collected from CWSs, these values do provide information on potential source waters. Importantly, the available non-targeted monitoring data that are associated with current use patterns show that detections of malathion were observed up to 23 ppb with detections over 1 ppb in 11 states and in some cases exceed modeled values shown in Table 1. This is important because these data likely do not correspond directly with what is expected to be maximum exposures. This is especially true for a short lived pesticide like malathion where sample frequency and timing of sampling relative to actual applications are key. Samples collected even a few days after a malathion application can easily miss the pulse of exposure associated with that event. EPA is investigating techniques to characterize the impact of sample frequency on predicted exposure from monitoring data but these are still under development and not currently applicable to malathion. But the concept applies to malathion in that most of the available monitoring data may miss true peak exposures. Therefore, any refinements considered must be cognizant of the lower bound on exposure provided by the available non-targeted monitoring data along with the uncertainty associated with that data.